



SENATE BILL 151 QUESTIONS AND ANSWERS

TRIPPLICATES OUT – NEW TAMPER-RESISTANT SECURITY PRESCRIPTIONS IN

Q What are “tamper-resistant security prescription” forms?

A The tamper-resistant security prescription forms are specialized prescription forms that have at least ten required security features pursuant to Health and Safety Code section 11162.1. As of July 1, 2004, the triplicate prescription forms, used for Schedule II controlled substances, is being phased out with a new tamper-resistant security prescription form that prescribers are required to purchase from designated security printers that have been approved by the Board of Pharmacy and the Department of Justice. By January 1, 2005, nearly all written controlled substance (Schedule II – V) prescriptions are required to be on these forms.

Q What is an *approved* “security printer”?

A A *security printer* is a printing company that has applied to and been *approved* by the Board of Pharmacy and the Department of Justice to produce the new tamper-resistant security prescription forms for use by authorized prescribers. If the security printer is not listed on the Board of Pharmacy website at http://www.pharmacy.ca.gov/app_sec_printers.htm, it is not approved, and cannot legally print the new security prescription forms.

Q How do I find an approved security printer to order the new tamper-resistant security prescription forms?

A Visit the Board of Pharmacy website at http://www.pharmacy.ca.gov/app_sec_printers.htm, choose a printing company from the list of approved security printers, and contact them directly to order the new prescription forms. Please have a copy of the prescriber’s state license and DEA registration available when you order. Prices differ and are set by each printer. If a company you wish to use is not listed on the Board of Pharmacy website, it is not an approved security printer and cannot legally print the new tamper-resistant security prescription forms. Unapproved printers can apply to the Board of Pharmacy for approval by completing the application found on our website at http://www.pharmacy.ca.gov/security_printer.htm.

Q Are triplicate prescription forms valid after July 1, 2004?

A Yes, triplicate prescription forms are valid through December 31, 2004. Prescribers can use either the triplicate prescription form or the new tamper-resistant security prescription form during the phase in period of July 1, 2004 through December 31, 2004 for Schedule II prescriptions. After January 1, 2005, nearly all written controlled substance prescriptions (Schedule II-V) must be on the new tamper-resistant security prescription form. Fax and oral prescriptions are still acceptable for Schedules III–V controlled substance prescriptions. However, a security feature on the new security form prints VOID across the face of the prescription when faxed, please use a regular prescription form for faxed prescriptions.

Q After January 1, 2005, what should prescribers do with their unused triplicate prescription forms?

A Please return unused triplicates to the Department of Justice, Triplicate Prescription Program, 4949 Broadway, Sacramento, California 95820 by certified or registered mail for destruction. For more information, please call (916) 227-4051.

Q How long is a controlled substance prescription valid?

A Since January 1, 2004, prescriptions for **all** controlled substances (Schedules II–V) are valid for 6 months from the date written. Pharmacists can disregard the 14-day restriction currently printed on the triplicate prescription form for Schedule II drugs; it is no longer correct.

Q Do I still have the option of faxing or phoning in a prescription for a Schedule III – V controlled substance?

A Yes, prescribers can fax or phone in a prescription for a Schedule III – V controlled substance. However, a security feature on the new tamper-resistant security prescription form prints VOID across the face of the prescription when faxed, please use a regular prescription form for faxed prescriptions. Pharmacies will have to validate the faxed prescriptions.

Q Can prescribers write a prescription for a non-controlled substance on the new tamper-resistant security prescription forms?

A Yes.

Q Can a prescriber write a non-controlled and a controlled substance prescription on one tamper-resistant security prescription form?

A Yes, as long as 1) the prescriber uses the security prescription blank that comes preprinted with the statement “Prescription is void if the number of drugs prescribed is not noted” and 2) the total number of drugs are written in the designated space on the security prescription form. See Health and Safety Code section 11162.1, subdivision (a)(8).

Q Can a prescription include more than one controlled substance (Schedules II - V) on the same tamper-resistant security prescription form?

A Yes, as long as 1) the prescriber uses the security prescription blank that comes preprinted with the statement “Prescription is void if the number of drugs prescribed is not noted” and 2) the total number of drugs are written in the designated space on the security prescription form. See Health and Safety Code section 11162.1, subdivision (a)(8).

Q Can a Schedule II controlled substance and a Schedule III controlled substance be written on the same tamper-resistant security prescription form?

A Yes, as long as 1) the prescriber uses the security prescription blank that comes preprinted with the statement “Prescription is void if the number of drugs prescribed is not noted” and 2) the total number of

drugs are written in the designated space on the security prescription form. See Health and Safety Code section 11162.1 subdivision (a)(8).

Q What replaces a skilled nursing facility/hospice pharmacy-generated triplicate prescription form (SNF form)?

A As of July 1, 2004, the pharmacy can use a form of its own design for those drug orders.

Q Can a California pharmacy fill a prescription for a Schedule II controlled substance that was written by an out-of-state prescriber for an out-of-state patient? What about Schedule III thru V controlled substances?

A Yes, so long as the prescription conforms to the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed. The prescription must be delivered to the patient in the other state. Prescriptions for Schedule II controlled substances must be reported to CURES and effective January 1, 2005, prescriptions for both Schedule II and III must be reported to CURES.

Q Is a federal controlled substance registration number the same thing as a DEA registration number?

A Yes

Q With the triplicates, the Department of Justice verified that a prescriber could write Schedule II controlled substance prescriptions prior to filling an order for triplicate forms. How does a pharmacist know that a prescriber has the authority to write controlled substance prescriptions using the new tamper-resistant security prescription form?

A Pursuant to Health and Safety Code section 11161.5 et seq., the approved security printer is required to verify that the prescriber ordering the new tamper-resistant security prescription forms, holds a valid unexpired license and has the authority to write controlled substance prescriptions (any or all Schedules II - V). If a pharmacist is concerned that a prescriber is not authorized to specifically write a Schedule II controlled substance prescription, the board recommends that the pharmacist ask the prescriber to provide a copy of his or her DEA registration, which lists the schedules of controlled substances that he or she is authorized to prescribe.

Q After January 1, 2005, can a prescriber use the Health and Safety Code section 11159.2 exemption for a terminally ill patient to write a prescription for any controlled substance (Schedule II – V) on a regular plain prescription form as long as the prescriber makes the notation “11159.2 exemption”?

A No, only Schedule II prescriptions for terminally ill patients can be written on a plain prescription form; there is no terminally ill exemption for Schedule III - V controlled substances. Effective January 1, 2005, prescriptions for Schedule III-V controlled substances for terminally ill patients must be either on a tamper-resistant security prescription form, telephoned, or faxed in to the pharmacy. The intent of the 11159.2 exemption is to make it easier for terminally ill patients to obtain strong pain medication. The exemption applies to Schedule II drugs, which can be written on a plain prescription form with the notation “11159.2 exemption”.

Q It appears that a pharmacist’s ability to correct an error or errors on a Schedule II prescription is eliminated on January 1, 2005, is that true?

A No, as of July 1, 2004, Health and Safety Code section 11164, subdivision (a)(5) allows a pharmacist to fill a Schedule II prescription containing errors if the pharmacist notifies the prescriber of the errors and the prescriber approves any correction. The prescriber must fax or mail a corrected prescription to the pharmacist within 7 days of the drug being dispensed. As of January 1, 2005, a Schedule II prescription containing errors should be handled as any other prescription that is uncertain, unclear, and/or ambiguous: the pharmacist must contact the prescriber to obtain the information to validate the prescription (Title 16 of the California Code of Regulations section 1761, subdivision (a).)

Q Do prescriptions for all controlled substances have to be entirely in the prescriber's handwriting?

A No, the prescriber is only required to sign and date controlled substance prescription, with limited exceptions.

Q Who can authenticate a controlled substance prescription? For example, verify a stamped signature, verify a prescription that appears to be copy, verify a typewritten date on a controlled substance prescription, or verify the source of new faxed-in prescription.

A Pharmacists using their professional judgment and training are responsible for interpreting and evaluating a prescription. However, at a pharmacist's direction a pharmacy employee may contact the prescriber's office to verify/clarify non-clinical information contained on a prescription; for example, is the fax/phone number that of the prescriber? Of course, a telephoned prescription must be received only by a pharmacist or pharmacist intern (under the supervision of the pharmacist). The pharmacist is responsible for the accuracy of all information on the prescription documents and the prescription medication dispensed.

Q If a prescriber has several offices, can he or she order the new tamper-resistant security prescription forms preprinted with all of the addresses listed?

A Yes, multiple addresses for one prescriber may be listed on the form. The forms may include a check box or some other means to identify the specific address where the patient was seen.

Q Can a prescriber purchase stock prescription blanks for a laser or dot matrix printer that comes with all of the security features except for the preprinted prescriber name, category of licensure, DEA number and state license number.

A No, the preprinted prescriber information is one of the security features and therefore, must be provided by an approved security printer. However, an approved security printer could offer for sale tamper-resistant security prescription blanks designed for laser or dot matrix printers as long as they are preprinted with the prescriber information before shipping to the prescriber. The prescriber could then send the patient and prescription information electronically to print on the laser prescription blank. The prescriber must sign and date the prescription.

Note: Although the prescriber address is not required to be printed on the prescription form by the approved security printer, the pharmacist cannot fill the prescription without the prescriber address on the form. Therefore, the board recommends that prescribers' order the new tamper-resistant security prescription forms with the address printed on the form. Multiple addresses are acceptable.

ORAL AND FAXED PRESCRIPTIONS

Q Can a prescriber call in or send a fax prescription for Schedule III – V controlled substances?

A Yes. For prescriptions called in to the pharmacist, the pharmacist must reduce the prescription to hard copy form using a form of the pharmacy's own design, and sign and date the prescription in ink. For faxed prescriptions, the pharmacist must produce the prescription in hard copy form, and sign and date the prescription in ink.

Note: One of the security features on the new tamper-resistant prescription forms will print "void" across the face of the security prescription when faxed or copied, prescribers are encouraged to use a regular prescription form when faxing prescriptions.

Q Can a prescriber call in or send a fax to a pharmacy for a Schedule II controlled substance?

A No, with two exceptions. A licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice can call in an order or send a fax prescription for Schedule II - V controlled substances. The pharmacist must reduce the prescription to hard copy on a form of the pharmacy's own design or produce the fax in hard copy form, and in both instances, must sign and date the prescription. (Health and Safety Code, section 11167.5.)

The other exception is for an emergency where loss of life or intense suffering may occur by not issuing the prescription pursuant to Health and Safety Code section 11167. In this instance, the prescriber may call in or fax the prescription to the pharmacy. The pharmacist must reduce the telephoned prescription to hard copy form, or produce the fax in hard copy form, and in both instances, sign and date the prescription. The prescriber must, within 7 days, provide a written prescription on the new tamper-resistant security prescription form (or triplicate form between July 1, 2004 and December 31, 2004). The pharmacist must notify the Bureau of Narcotic Enforcement within 144 hours of a prescriber's failure to do so, including the date and method of notification.

Q Can a prescriber's staff person call in or send a fax for a Schedule III – V prescription?

A Yes, however, the prescription must include the name of the person calling in or faxing the prescription. A pharmacist or pharmacist intern must receive a telephone order. In addition, the pharmacist must authenticate the validity of the prescription.

LICENSED HEALTH CARE FACILITIES

Q Can a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice call in or fax a Schedule II controlled substance order for a patient? What if the patient is being discharged and wants to pick up the prescription on the way home at the pharmacy?

A An order for a Schedule II controlled substance for a patient of a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or a licensed hospice can be phoned in or faxed pursuant to Health and Safety Code section 11167.5. Phoned in orders must be reduced to hard copy and signed and dated by the pharmacist. Faxed orders must be produced in hard copy form, and signed and dated by the pharmacist. The prescription must include the signature of the person receiving the controlled substance prescription on behalf of the facility. The facility must forward a copy of any signed telephone orders, chart orders, or related documentation to the pharmacist.

Discharged patients receive a written prescription as outpatients; therefore, the prescription must be written on the new tamper-resistant security prescription form or the triplicate form from July 1, 2004 through December 31, 2004. After January 1, 2005, the order must be written on the new tamper-resistant security prescription form.

Q What is an “institution” form for a qualified licensed health care facility?

A A *licensed health care facility* has the option of designating a prescriber to represent the health care facility. The designated prescriber’s name, state license number, category of licensure, and DEA number are preprinted on the prescription form along with the facility name, address, state license number, and category of licensure. The form also includes a blank space for the actual prescriber to handwrite, type, or stamp his or her name, state license number, category of licensure, and DEA number. The forms are delivered to the designated prescriber who is responsible for distributing the prescription forms to prescribers authorized within the facility. The designated prescriber must maintain a record that includes the name, category of licensure, state license number, DEA number, and the quantity of forms issued to each prescriber and maintain the record in a readily retrievable format for 3 years. The designated prescriber may delegate any or all of these tasks to staff; however, the designated prescriber will be held accountable for compliance with these requirements. The board recommends that the prescriber also record the batch/lot numbers of the forms distributed. (Health & Safety Code section 11162.1, subdivision (c).)

CALIFORNIA UTILIZATION, REVIEW, AND EVALUATION SYSTEM (CURES)

q What is CURES?

A The Department of Justice, Bureau of Narcotics Enforcement maintains the California Utilization, Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances dispensed to patients in California pursuant to Health and Safety Code section 11165. The CURES database captures data from all Schedule II controlled substance prescriptions filled as submitted by pharmacies, hospitals, and dispensing physicians. Beginning January 1, 2005, CURES will capture Schedule III data as well. Law enforcement and regulatory agencies use the data to assist in their efforts to control the diversion and resultant abuse of Schedule II and III drugs. Prescribers and pharmacists may request a patient’s history of controlled substances dispensed in accordance with guidelines developed by the Department of Justice.

Q Who is required to report to CURES?

A All dispensing pharmacies authorized to **dispense** Schedule II drugs are required to report to CURES in a frequency and format specified by the Department of Justice, Bureau of Narcotic Enforcement (BNE). BNE requires pharmacies to submit data in an electronic format by the 18th of every month, the data collected from the previous month. Beginning January 1, 2005, both Schedule II and III prescriptions filled must be reported to CURES. The BNE directs pharmacies to contact the CURES data collection vendor, Atlantic Associates, at 1-888-492-7341 for information on how to submit data.

As of July 1, 2004, physicians that dispense Schedule II drugs from their offices directly to patients must report to CURES in hard copy or in an electronic format, and beginning January 1, 2005, all Schedule III drugs dispensed must also be reported. Dispensing physicians should contact the Department of Justice, Bureau of Narcotic Enforcement, at (916) 227-4051 for more information.

Q How does a pharmacy submit data to the CURES system?

A The Department of Justice, Bureau of Narcotic Enforcement specifies pharmacies to submit data for the previous month to CURES no later than the 18th of every month. Pharmacies must report electronically or via disk accompanied by a completed CURES Program Transmittal form. Pharmacies are required to report even if they did not fill any Schedule II prescriptions; reported as zero on the CURES Program Transmittal form. BNE directs pharmacies to contact the data collection vendor, Atlantic Associates, toll free at 1-888-492-7341 for more detailed information and data format specifications.

Q How does a prescriber or pharmacist request a patient history of controlled substances prescriptions from the CURES system?

A A prescriber or pharmacist can download a Patient Activity Report (PAR) request form by visiting the Board of Pharmacy website at https://www.dca.ca.gov/pharmacy/secure/pharmacy_forms_request.htm. Complete the appropriate PAR form and fax it to the Department of Justice, Bureau of Narcotic Enforcement at (916) 227-5079.

Q Do I need to enter the batch/lot number on the new tamper-resistant security prescription form into CURES?

A No, the batch/lot number is not tracked by the State. The batch number is not reported to the CURES system. Prescribers might consider using the batch number to track their forms internally for inventory purposes, and security printers might consider using the number to account for forms during the production process.

Q Can a physician have more than one DEA number?

A Yes. A physician who administers or dispenses controlled substances directly to their patients in the office, pursuant to Business and Professions Code section 4170, are required to have a separate DEA registration number for every address from which he or she practices. If the physician only writes prescriptions for their patients to take to a pharmacy to dispense, then he or she is only required to have one DEA number for all practice addresses.

Q I am a prescriber who dispenses controlled substance prescriptions to patients in my office. Do I need to report the information to the CURES system? If so, how do I report to CURES?

A As of July 1, 2004, prescribers that dispense Schedule II drugs directly to patients in their office are required to report to CURES in a hard copy or electronic format, and effective January 1, 2005, all Schedule III drugs must be reported as well. Prescribers, such as medical doctors, dentists, podiatrists, veterinarians, optometrists, midwives, and nurse practitioners, must meet all of the requirements for dispensing controlled substances pursuant to Business and Professions Code section 4170, such as labeling and packaging requirements, and providing patients the option of receiving a prescription. The Department of Justice, Bureau of Narcotic Enforcement (BNE), is in the process of developing a method for dispensing prescribers to submit data to CURES. For more information, please contact the BNE at (916) 227-4051.

Note: Prescribers that provide their patients written prescriptions to take to the pharmacy, or sends a fax or phones in prescriptions to a pharmacy are not required to report to CURES. The pharmacy is required to report those prescriptions to CURES.

Q Our pharmacy's volume of Schedule II controlled substances dispensed is less than 25 per month and sometimes-even zero for a month; do I still need to report to CURES?

A Yes, currently all Schedule II prescriptions dispensed, and effective January 1, 2005, all Schedule II and III prescriptions dispensed, must be reported to CURES. The Department of Justice, Bureau of Narcotic Enforcement (BNE) requires pharmacies to submit data in an electronic format. Pharmacies must also report any month that they did not fill any Schedule II or III prescriptions by marking zero under the "*Total number of prescriptions included*" on the CURES Program Transmittal Form. For more information or to obtain blank transmittal forms, BNE directs pharmacies to contact the data collection vendor, Atlantic Associates, at 1-888-492-7341.

Q Does the pharmacy still need to send a copy of the Schedule II prescription to the Department of Justice?

A During the phase in period, July 1, 2004 through December 31, 2004, if the pharmacy receives a Schedule II prescription on a triplicate form, the pharmacy must send the copy to the Department of Justice as well as report the data in an electronic format to CURES. If the pharmacy receives the prescription on the new tamper-resistant security prescription form, only the data is transmitted to CURES.

Q What does a pharmacist enter into the triplicate number field in CURES when the prescription is written on the new tamper-resistant security prescription form?

A Between July 1, 2004 and December 31, 2004, if the Schedule II prescription is written on a triplicate prescription form, enter the triplicate number into CURES. If the prescription is written on the new tamper-resistant security prescription, enter all zeros or leave the triplicate field blank.